Ironwood Pharmaceuticals Provides First Quarter 2011 Investor Update

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today provided an update on its recent and first quarter 2011 business activities.

First Quarter 2011 and Recent Highlights

Linaclotide

- Ironwood and its U.S. partner, Forest Laboratories, Inc., recently presented six linaclotide ‑ related abstracts at the 2011 Digestive Disease Week (DDW) annual meeting in Chicago. These presentations were the first time that Ironwood and Forest discussed the full results of the two Phase 3 IBS ‑ C clinical trials that were completed in the second half of 2010.
- Ironwood and Forest are on track to submit a New Drug Application (NDA) for linaclotide with the U.S. Food and Drug Administration for both the irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC) indications in the third quarter of 2011.
- Ironwood's European partner, Almirall, S.A., is on track to submit a Market Authorization Application (MAA) for linaclotide with the European Medicines Agency for the IBS ‑ C indication in the second half of 2011.

Pipeline

- Ironwood continues to advance its pipeline, which includes product candidates and research efforts focused on gastrointestinal disease, pain and inflammation, respiratory and allergic disease, and cardiovascular disease.

Corporate

- Ironwood ended the first quarter of 2011 with approximately $221 million of cash, cash equivalents, and available-for-sale securities. Ironwood used approximately $24 million of cash for operations. Based on its current operating plan, Ironwood continues to target ending fiscal year 2011 with greater than $150 million of cash, cash equivalents, and available-for-sale securities.

Conference Call Information

Ironwood will host a conference call and webcast at 8:30 a.m. Eastern Time today to discuss its business activities, including its commercial strategy for linaclotide. Individuals interested in participating in the call should dial (888) 820-9416 (U.S. and Canada) or (913) 312-1416 (international) using conference ID number 1229502. To access the webcast, please visit the Investors section of Ironwood's website at www.ironwoodpharma.com at least 15 minutes prior to the start of the call to ensure adequate time for any software downloads that may be required. The call will be available for replay via telephone starting today at approximately 11:30 a.m. Eastern Time, running through 11:59 p.m. Eastern Time on May 26, 2011. To listen to the replay, dial (888) 203-1112 (U.S. and Canada) or (719) 457-0820 (international) using conference ID number 1229502. The archived webcast will be available on Ironwood's website for 14 days beginning approximately one hour after the call.

About Linaclotide

Linaclotide, an investigational drug, is an agonist of the guanylate cyclase type-C (GC-C) receptor located on the luminal surface of the intestine. In preclinical models, linaclotide reduced visceral hypersensitivity, increased fluid secretion, and accelerated intestinal transit. The effects on secretion and transit are mediated through cyclic guanosine monophosphate (cGMP), which is also believed to modulate the activity of local nerves to reduce pain. Linaclotide is an orally delivered peptide that acts locally in the gut with no measurable systemic exposure at therapeutic doses and is intended for once-daily administration. Linaclotide is in Phase 3 clinical development for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The efficacy portion of linaclotide's development program has been completed and will support the NDA submission for both indications, as well as the MAA submission for the IBS-C indication. Long-term safety studies are underway. In Phase 3 efficacy studies, the most commonly reported side effect was diarrhea. Most events of diarrhea were reported as mild to moderate. An issued composition of matter patent for linaclotide provides protection to 2025. Ironwood and Forest are co-developing and, if it is approved, will co-promote linaclotide in the United States. Ironwood has out-

licensed linaclotide to Almirall for European development and commercialization, and to Astellas Pharma Inc. for development and commercialization in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

About Irritable Bowel Syndrome with Constipation (IBS-C)

IBS-C is a chronic functional gastrointestinal disorder characterized by abdominal pain, discomfort, and bloating associated with altered bowel habits, and as many as 13 million people in the U.S. suffer from it. There are currently few available therapies to treat this disorder and there is a high rate of dissatisfaction with available therapies. Patients suffering from IBS-C can be affected physically, psychologically, socially, and economically.

About Chronic Constipation (CC)

As many as 26 million Americans suffer from symptoms associated with CC and 8.5 million patients have sought treatment. Patients with CC often experience hard and lumpy stools, straining during defecation, a sensation of incomplete evacuation, and fewer than three bowel movements per week, as well as discomfort and bloating. This condition significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities. There is a high rate of dissatisfaction with currently available treatments.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Linaclotide, Ironwood's GC-C agonist, is in Phase 3 clinical development for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. The efficacy portion of linaclotide's development program has been completed and will support the NDA submission for both indications, as well as the MAA submission for the IBS-C indication. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass. To learn more, visit www.ironwoodpharma.com.

This press release contains forward looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, the timing of the filing of a New Drug Application or a Marketing Authorization Application for linaclotide, linaclotide's potential as a treatment for IBS-C or chronic constipation, our commercial manufacturing efforts for linaclotide, and our targeted cash-on-hand for 2011. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include the risks that our linaclotide development activities do not progress as expected, serious adverse events arise in patients that are deemed to be definitely or probably related to linaclotide treatment, and the incidence or severity of diarrhea in patients treated with linaclotide is higher than expected, as well as risks related to the difficulty of predicting regulatory approvals, and the acceptance of and demand for new pharmaceutical products. Applicable risks also include those that are listed in our Annual Report on Form 10-K for the year ended December 31, 2010, in addition to the risk factors that are listed from time to time in Ironwood Pharmaceuticals' Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings. We undertake no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. These forward-looking statements speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement.

Condensed Consolidated Balance Sheets

(in thousands)
(unaudited)

	March 31, 2011	December 31, 2010
Assets		
Cash, cash equivalents and available-for-sale securities	$ 220,569	$ 248,027
Accounts receivable, net	4,184	2,895
Prepaid expenses and other assets	4,299	8,153
Total current assets	229,052	259,075
Property and equipment, net	35,074	34,369
Other assets	7,898	7,921
Total assets	$ 272,024	$ 301,365
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	$ 17,364	$ 21,380
Current portion of capital lease obligations	241	197

Current portion of deferred rent	2,877	2,799
Current portion of deferred revenue	40,050	40,050
Total current liabilities	60,532	64,426
Capital lease obligations	598	393
Deferred rent	13,939	14,612
Deferred revenue	52,370	62,383
Total stockholders' equity	144,585	159,551
Total liabilities and stockholders' equity	$ 272,024	$ 301,365

Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2011	**2010**
Revenue	$ 10,237	$ 8,838
Operating expenses:		
Research and development	19,555	17,549
General and administrative	9,224	5,785
Total operating expenses	28,779	23,334
Loss from operations	(18,542)	(14,496)
Other income (expense), net	141	15
Net loss from continuing operations	(18,401)	(14,481)
Net loss from discontinued operations	—	(1,772)
Net loss	(18,401)	(16,253)
Net loss from discontinued operations attributable to noncontrolling interest	—	329
Net loss attributable to Ironwood Pharmaceuticals, Inc.	$ (18,401)	$ (15,924)
Net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted:		
Continuing operations	$ (0.19)	$ (0.23)
Discontinued operations	—	(0.02)
Net loss per share	$ (0.19)	$ (0.25)
Weighted average number of common shares used in net loss per share attributable to Ironwood Pharmaceuticals, Inc.—basic and diluted	99,075,187	63,957,966

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Source: Ironwood Pharmaceuticals, Inc.